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Abaraogu, Ukachukwu Okoroafor; Dall, Philippa; Seenan, Chris

Published in:
BMJ Open

DOI:
[10.1136/bmjopen-2016-011405](https://doi.org/10.1136/bmjopen-2016-011405)

Publication date:
2016

Document Version
Publisher's PDF, also known as Version of record

[Link to publication in ResearchOnline](#)

Citation for published version (Harvard):
Abaraogu, UO, Dall, P & Seenan, C 2016, 'Patient education interventions to improve physical activity in patients with intermittent claudication: a protocol for a systematic mixed-studies review', *BMJ Open*, vol. 6, no. 5, e011405, pp. e011405. <https://doi.org/10.1136/bmjopen-2016-011405>

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BMJ Open Patient education interventions to improve physical activity in patients with intermittent claudication: a protocol for a systematic mixed-studies review

Ukachukwu Okoroafor Abaraogu,^{1,2} Philippa Margaret Dall,¹ Christopher Andrew Seenan¹

To cite: Abaraogu UO, Dall PM, Seenan CA. Patient education interventions to improve physical activity in patients with intermittent claudication: a protocol for a systematic mixed-studies review. *BMJ Open* 2016;**6**: e011405. doi:10.1136/bmjopen-2016-011405

► Prepublication history and additional material is available. To view please visit the journal (<http://dx.doi.org/10.1136/bmjopen-2016-011405>).

Received 4 February 2016
Revised 8 April 2016
Accepted 3 May 2016



CrossMark

¹School of Health and Life Sciences, Glasgow Caledonian University, Glasgow, UK

²Department of Medical Rehabilitation, University of Nigeria Enugu Campus, Enugu, Nigeria

Correspondence to

Ukachukwu Okoroafor Abaraogu;
Ukachukwu.Abaraogu@gcu.ac.uk,
Ukachukwu.Abaraogu@unn.edu.ng

ABSTRACT

Introduction: Peripheral arterial disease (PAD) and intermittent claudication (IC) decrease an individual's capacity to engage in physical activity (PA) with potentially negative effects on PA behaviour. Strategies to improve PA among this population may provide a range of positive health benefits. We present a protocol to assess the components of patient education interventions that improve PA capacity and PA behaviour in patients with PAD and IC.

Methods and analysis: Published peer-reviewed studies will be searched in the following databases: CINAHL, the Cochrane Library, OVID, ProQuest, AMED, MEDLINE, PsycINFO, Web of Science Core Collection and PEDro, to identify literature investigating the effect of patient education on PA of patients with PAD and IC, or studies that investigated patients' perceptions or experience with these interventions. Two authors will independently perform screening for study eligibility, result synthesis and then appraise study quality. For interventions without follow-up, primary outcome measures will include change in PA capacity, or change in free-living PA behaviour; where there was a follow-up postintervention, the primary outcome will be rate of adherence to PA behaviour improvement. A three-phase sequential explanatory synthesis of mixed studies will be employed to answer the research questions. Homogenous quantitative data will be analysed using a random-effects model of meta-analysis with results presented as relative risk for dichotomous outcomes and as weighted or standardised means for continuous outcomes. Qualitative data will be analysed using thematic synthesis. This review protocol is reported according to the Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P) 2015 guidelines.

Trial registration number: CRD42015027314.

INTRODUCTION

Peripheral arterial disease (PAD) is a common, chronic, vascular condition

affecting more than a quarter of a billion people in the world.¹ Between 2000 and 2010, in developed countries, there was a 13% rise in the prevalence of this debilitating condition.¹ The primary symptom associated with PAD is intermittent claudication (IC),² which is described as lower limb pain or discomfort that is induced by walking and relieved by rest.^{3–4} Owing to the pain associated with walking, patients with IC suffer mobility impairment and loss of control,⁵ which have a negative impact on physical and social functions.⁶ The eventual outcomes of this are major limitations in the activities of daily living,⁷ with decreasing quality of life. In addition, the resultant decreased ability to engage in physical activity (PA) and the attendant deterioration in PA behaviour may further compromise cardiovascular health, potentially leading to an increased risk of a future cardiovascular event⁸ in a vascular system already compromised by PAD.⁹

Conservative treatments are usually the recommended approach to managing patients with IC.¹⁰ These include risk factor modification, antiplatelet therapy and walking exercise programmes. Despite the fact that these interventions have shown demonstrable effectiveness in terms of improvement in PA capacity (walking ability) when assessed in the laboratory,^{11–17} translation to free-living PA behaviour improvement has rarely been demonstrated. Furthermore, because PAD is a chronic condition requiring long-term management, there is also the potential for adverse effects of long-term use of medication, most of which have only a modest benefit.^{18–19} Additionally, a Cochrane review reported that patients' compliance

with exercise instruction is a major challenge.²⁰ Patients' adherence is important because it may have an impact on the effectiveness of an intervention. One common approach to facilitating risk factor modification, particularly in chronic, non-communicable disease management, is patient education.²¹ Patient education has been reported to improve PA behaviour among individuals with stroke²² and chronic obstructive pulmonary disorders.²³

There is not yet a consensus regarding the form of interventions centred on patient education for improving PA capacity and behaviour of patients with IC. Two previous reviews on home-based exercise programmes,²⁴ and behaviour-change techniques²⁵ for individuals with IC have been conducted. Galea *et al*²⁴ only included randomised controlled trial (RCT) studies in their review. In the context of complex, non-pharmacological interventions, such as patient education, this excludes potentially relevant evidence derivable from other study designs. In addition, both reviews^{24 25} were primarily interested in PA capacity instead of free-living PA behaviour as the primary outcome and did not set out to consider the qualitative experience or perspective of patients to interventions aimed at improving PA among this population. To develop a potentially effective education intervention to improve free-living PA behaviour, a clear understanding of the components required for effectiveness and for optimum adherence of patients to these interventions is needed. Similarly, the assessment of how these interventions translate into free-living PA behaviour should be considered. A systematic review of the literature is warranted to explore the quantitative and qualitative research evidence and to determine the effective components of education interventions for patients with PAD and IC. This article aims to report on the protocol for a systematic mixed-studies review of the topic and will be reported according to the Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P) 2015 guidelines.^{26 27}

METHODS

Aim and review questions

The aim of this systematic mixed-studies review will be to determine the effective components of patient education for improving PA in individuals with IC through evidence from the quantitative and qualitative research. Specific objectives will include the following: (1) to determine the effectiveness of patient education interventions in improving PA capacity and/or PA behaviour in patients with IC and (2) to investigate experiences and perceptions of patients with IC regarding patient education interventions aimed at improving their PA capacity and/or PA behaviour.

The proposed review will mainly seek to address the question: 'What constitutes the effective components of education interventions for patients with IC based on reports from published literature?' To achieve the research objectives above, two secondary research

questions to be answered are: 'Are education interventions effective in improving PA capacity and PA behaviour in patients with IC?' and 'What are the patient experiences and perceptions of education interventions aimed at improving their PA capacity and/or PA behaviour?'

Design

The protocol for this review has been registered with the International Prospective Register of Systematic Reviews (PROSPERO, CRD42015027314). A two-stage mixed-studies review design approach will be employed. The first stage will describe the studies meeting prior broad eligibility criteria. Then, studies meeting a narrower set of criteria will be pooled, potentially enabling a meta-analysis in the second stage.

Eligibility criteria

Studies will be considered for eligibility according to the following criteria.

Types of studies

Original research manuscripts in peer-reviewed journals and conference proceedings will be included if published in the English language. There will be no restrictions on the type of study design. Studies will be eligible if one of the following was evaluated: the effect of education interventions in patients with IC; the factors that influence adherence to these interventions; the factors that influence the effectiveness of the interventions; and the experiences or perceptions of patients to education interventions. RCTs and non-RCTs will be included in the review, including quasi-RCTs, controlled clinical trials, cross-over trials, controlled before and after trials and non-controlled before and after studies.

Types of participants

Studies involving adult human participants aged ≥ 18 years will be eligible for inclusion. Studies involving participants with symptomatic IC due to PAD will be included. The basis for the diagnosis of IC may be objective (eg, an ankle-brachial index (ABI) < 0.9 , evidence of PAD on Doppler ultrasound or angiography), or by questionnaire. If objective measures were not used or reported, then studies reporting a clinical diagnosis will be included. Only studies where all the participants have a diagnosis of IC will be included. Studies with participants with critical limb ischaemia will be excluded. No particular restrictions will be considered regarding the setting of studies to be included. Therefore, studies conducted in health centres, clinics, hospitals or community settings will be included.

Types of interventions

Patient education interventions for patients with PAD and IC will be considered for inclusion. Inclusion will not be restricted to a particular form, dose, frequency, intensity, duration of intervention or follow-up period after intervention. For many studies, the intervention

may be complex and may include exercise, medication, nutrition, psychological interventions and social interventions, in addition to the education component. Such studies will be included as long as the effect of patient education intervention can be determined. Specifically, search terms will not be restricted to the term 'education'. Studies with other terminologies including, but not limited to, home-based exercise, behavioural modification and self-management interventions will be included in the review. An intervention will be included if it is a structured education aimed at PA behavioural modification. Interventions consisting of simple instructions to 'go home and exercise' or advice to 'change lifestyle' will not be considered as a patient education intervention. Studies with any type of control group will be included, as well as studies with pretest–post-test design with without a control.

Types of outcome measures

Studies which report changes in outcome measures of free-living PA behaviour (eg, daily step counts, self-report of improvement in PA behaviour), adherence to these PA behaviour changes, change in PA capacity (eg, pain-free walking distance, maximal walking distance, walking time to onset of pain, maximum walking time) or outcomes of patients' experiences with interventions will be included in the review. In addition, studies which report on other clinical outcomes, such as pain, quality of life (if measured with a generic valid instrument) and psychological outcomes (eg, self-efficacy, confidence, self-esteem, social functioning and coping) will be eligible for inclusion. Studies will be included whether or not an outcome of interest is reported as a primary or secondary outcome in the original article, so long as a distinct analysis was conducted for each outcome. Studies will be included if they assess any of the outcomes reporting PA capacity or free-living PA behaviour. The basis of how PA capacity or free-living PA behaviour was measured will not be used as a reason for exclusion. All outcome variables will be collected as they are reported in individual studies, and their original description in these individual studies will not be altered. Clinical outcomes, or their close surrogate, reported by individual studies will be analysed and graded.

Exclusion criteria

Studies without patient education interventions or patients' perception of these interventions will be excluded from the review. Narrative review syntheses, systematic reviews, opinion papers, letters to the editor and any study not including primary data or a clear method of data analysis will also be excluded. Finally, duplicate publications from the same study will be excluded. In this case, the most comprehensive or most recent publication will be used.

Information sources and search strategy

A comprehensive and sensitive search strategy was developed and piloted (see online supplementary

appendix 1). This strategy was developed in accordance with the guidelines of the Cochrane Handbook for Systematic Reviews,²⁸ and the recommendations for Health Care Review by the Centre for Reviews and Dissemination.²⁹ This search strategy will be performed in two steps. The first step will be to identify studies in bibliographic databases and search for grey literature. The second step will be selection of studies for inclusion based on prior eligibility criteria.

Studies will be identified using the previously developed search strategy (see online supplementary appendix 1), to search the following databases: CINAHL, the Cochrane Library, OVID, ProQuest, AMED, MEDLINE, PsycINFO, Web of Science Core Collection and PEDro. Trial registers and directory of open-access repository websites including <http://www.clinicaltrial.gov>, <http://www.opendor.org> and the Web of science conference proceedings will also be searched. Additionally, searches will be performed from the reference lists of identified studies.

Study records and data management

Literature search results will be exported into RefWorks to check for duplication of studies. Bibliographic records will be exported from RefWorks into Microsoft Excel (Microsoft. Microsoft Excel. Redmond, Washington: Microsoft, 2010. Computer Software) to facilitate the management and selection of articles for inclusion. The review team will then develop, pilot and, if required, refine eligibility questions and forms for the studies included within the review.

Selection processes

Initial screening will be conducted simultaneously on the title and abstract by one reviewer to identify potentially relevant studies. A second review author will cross-check these initial screening results. Two reviewers will then read through the full text of selected studies for further screening, again using the prior eligibility criteria. Any difference of opinion occurring at any stage regarding inclusion or exclusion will be resolved by discussion and reflection, in consultation with the third reviewer if required. If a decision cannot be made based on available information, study authors will be contacted (to the maximum of three email attempts) to clarify issues of selection of any study. If an author does not respond, the study will be excluded and the reason for exclusion recorded. Details of the flow of studies throughout the process of assessment of eligibility and study selection will be presented, along with the reasons for exclusion at each stage of the process, in a flow chart (PRISMA diagram).

Data collection processes

Quality appraisal for included studies

The Mixed Methods Appraisal Tool (MMAT)³⁰ will be employed to assess the quality of included studies. The use of MMAT is to enable a valid, efficient and reliable

assessment of the quality of the quantitative and qualitative studies at the same time.^{30 31} Using this tool, the studies will be assessed for the suitability of their study design to the research objectives, risk of bias of included studies, outcome measures, statistical issues, quality of reporting, intervention quality and generalisability of the study results.

Two reviewers will perform the data extraction independently. Any disagreement regarding study eligibility will be resolved by discussion and reflection, in consultation with a third reviewer if required. The Data Extraction Template developed by the Cochrane Consumers and Communication Review Group³² will be adapted to extract quantitative data from the quantitative studies. The Supplementary Guidance for Inclusion of Qualitative Research in Cochrane Systematic Reviews of Interventions³³ will be used to extract qualitative data from the included studies.

Data items

Data will be collected from variables including authors' reference, participants' characteristics (including age range, gender composition, inclusion and exclusion criteria), study sample size (also the sample size of groups, where available), criteria used in diagnosing IC, study design, components of the intervention, context of the intervention, who delivered the intervention, the duration of the intervention and follow-up (where available), attrition rate, outcome(s) assessed, the outcome measurement methods/techniques, results, conclusions and funding sources.

Outcomes and prioritisation

The main outcomes in the review will be PA behaviour outcomes (daily step counts, time spent walking, number of walking events, self-report of improvement in PA behaviour), adherence to PA behaviour improvement where there was a follow-up postintervention, and patients' experiences to intervention—responses to question on patient perception of interventions.

For interventions without follow-up, the primary outcome measures will be change in daily step counts and self-reported change in PA behaviour. Where there was a follow-up postintervention, adherence to changes in these PA behaviour outcomes will also form the primary analysis. Separate analysis will be conducted for each outcome. Secondary outcomes will assess patients' experiences with the intervention, patients' perception of interventions and PA capacity outcomes (eg, pain-free walking distance, maximal walking distance, pain-free walking time, maximal walking time). In addition, other clinical outcomes such as pain and quality of life (if measured with a generic valid instrument), and psychological outcomes (eg, self-efficacy, confidence, self-esteem, social functioning and coping) will be assessed as secondary outcomes.

Definitions used in the original included studies will be used for all outcomes. Only data for the first period

of outcome assessment will be included for cross-over studies in order to avoid a cross-over effect.

Risk of bias assessment in individual studies

Using the Cochrane Collaboration Tool for Risk of Bias Assessment (Table 8.5a of the Cochrane Handbook for Systematic Reviews of Interventions),²⁸ risk of bias for each of the intervention studies will be evaluated in six key domains: (i) selection bias (random sequence generation, allocation concealment); (ii) performance bias (blinding of personnel and participants); (iii) detection bias (blinding of outcome assessments); (iv) bias due to attrition (incomplete outcome data, including dropouts and withdrawals); (v) reporting bias (selective reporting) and (vi) other bias (other sources of bias not elsewhere addressed). Assessment will be made in each of the included studies, and they will be graded as 'high risk' or 'low risk' following a well-described procedure (Table 8.5.d of the Cochrane Handbook for Systematic Reviews of Interventions).²⁸ Then, summary assessment for each important outcome (across domains) within and across studies will be conducted (Table 8.7.a of the Cochrane Handbook for Systematic Reviews of Interventions).²⁸ When there is inadequate detail in a study to make a judgement, the risk of bias in that study will be reported as unclear. In such cases, the study authors will be contacted to provide the required information. Two reviewers will make judgements regarding the risk of bias independent of each other. Areas of differences will be resolved by discussion and reflection, or in consultation with the third reviewer. Appraisal of the quality of the included studies will only be carried out after study selection has been completed, and during data extraction and synthesis. After this, the strength of evidence for this review will be reported.

RESULTS

This section of the protocol reports the planned data analysis of the review.

Data synthesis including assessment of heterogeneity

A three-phase sequential explanatory synthesis of mixed studies will be employed to answer the research questions.³⁰ In the first phase, the question of the effectiveness of patient education intervention will be answered. In doing this, all quantitative study results which examined the effectiveness of these interventions will be presented, compared and pooled in an evidence table. The effectiveness of patient education interventions will be established by conducting a meta-analysis of the effects.³⁰ Data from quantitative studies that cannot be analysed statistically will be interpreted using narrative synthesis.

The second phase will seek to answer questions regarding the attitude, experiences and perception of patients to these interventions using information from data from the study results. In doing this, qualitative

thematic analysis will be used to integrate the results of the qualitative studies and the qualitative results of mixed-methods studies.³⁰ Interpretation of the second phase results will be used to establish the beneficial and non-beneficial aspects of the interventions from the patients' point of view.

Finally, in the third phase, interpretation of the first and second phases will be carried out to answer the overall objective of the systematic review: 'What are the effective components of patient education interventions for improving PA capacity and PA behaviour in patients with IC?' The effective components of the interventions will be inferred by comparing the effectiveness of the interventions that contained the useful components identified from qualitative results with the interventions that did not contain these components.

Characteristics of the retained studies sorted by year of publication will be presented in a tabular form using two different tables.³¹ One table will describe the quantitative data from intervention studies, while the other will describe qualitative studies. Both tables will have information relating to authors' references, study designs, sample size, gender, age, study objectives, setting (rural vs urban), data collection format, outcomes or themes.^{32 33} In addition, the table for intervention studies will contain information on scales used to assess outcome, intervention objectives, components of the intervention, component of the control, format and provider of the intervention, setting of the intervention (home/community vs hospital), intervention and follow-up periods, and results.³⁴

Quantitative data analysis

Analysis and presentation of results will be made in hierarchical order with the primary outcomes (relating to PA behaviour change) coming before the additional outcomes. It is anticipated that there may be significant heterogeneity in terms of clinical characteristics of participants, diverse populations studied, different interventions provided, study designs, statistical strategy and outcomes used. Hence, heterogeneity will be assessed using Cochran's χ^2 test (at 10% α level) and further quantified using I^2 to decide which effect models to use for meta-analysis.³⁵ It is expected that there will be heterogeneity that cannot readily be dealt with. Accordingly, studies with homogenous characteristics in terms of design, intervention and comparator will be pooled together for meta-analysis using a random-effects model (9.5.4 Incorporating heterogeneity into random-effects models).²⁸ Other heterogeneous studies will be interpreted using narrative synthesis following the recommendation of the Centre for Reviews and Dissemination to explore the relationship and findings between and within the included studies.²⁹

In conducting the meta-analysis, the statistical approach will be to compare the absolute change in means from the baseline (and the 95% CIs) following intervention where baseline data are available, or to

compare change in the intervention group versus control groups. Otherwise, the relative percentage change between postintervention values in the intervention and control groups will be compared. When an outcome is assessed using dichotomous scales, the relative risk (RR, and associated 95% CI) will be used to assess treatment effects where possible. All continuous outcomes will be assessed using the weighted mean difference or, when different measurement scales are used, the standardised mean difference. Skewed data and non-quantitative data will be reported descriptively. All adverse effects reported in the included studies will be recorded. Data analysis will be completed using RevMan V.5.3 (Review Manager (RevMan) [Computer program]. V. 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014).

Sensitivity analysis

Subgroup analysis will be limited to the primary outcome (PA behaviour outcomes) and one secondary outcome (PA capacity outcomes). Multiple subgroup analyses will be conducted to ascertain the potential influence of difference in intervention setting (hospital vs home/community based), habitation setting (rural vs urban habitation), design (RCTs vs non-RCTs) and intervention type (structured education intervention vs passive provision of information) in meta-analysis outcome/effect size/treatment effect direction.

Publication bias

Data from studies published only as abstracts, where available, will be combined to the review data to conduct meta-analyses to see if such addition influences the forest plot. The impact of publication bias will be investigated using the funnel plot for asymmetry and Egger's regression test.³⁵

Qualitative data analysis

A thematic synthesis method for qualitative research in systematic reviews described by Thomas and Harden will be used to synthesise the qualitative data.³⁶ This methodology will follow somewhat overlapping three stages: (i) free line-by-line coding of the findings of included studies; (ii) organisation of these 'free codes' into related areas to construct 'descriptive' themes and (iii) development of 'analytical' themes from the interpretation and abstraction of the descriptive themes into higher order explanations. The review team will validate each of these stages of qualitative analysis by comparing the generated codes and themes with the results of the primary studies.

Confidence in cumulative evidence

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach will be used to judge the quality of evidence of the studies to determine the confidence in cumulative estimates in the systematic review.³⁷ Each study will be assessed across the domains of risk of bias including consistency, directness,

precision and publication bias. Adopting this approach, a study will be rated as high where further research is unlikely to change the effect estimates, moderate where further research is likely to have an important impact on the effect estimates or change the estimate, low where further research is very likely to have an important impact on the effect estimates and change the estimate, or very low where the estimate of effects is extremely uncertain.

How this review will be reported

This systematic review will be reported according to the PRISMA statement, with all items relevant to the review included. A PRISMA checklist applicable to this review will be published with the final report.³⁸

Dealing with protocol amendments during and after review

In order to avoid the introduction of outcome reporting bias, amendments will not be made on the quantitative aspect of this review protocol based on the findings from the included studies. This precaution is being taken because publication bias easily affects quantitative studies with the effect easy to identify. However, any justified unanticipated amendment, potentially arising from a clearer understanding of the review questions, will be documented and implemented. In the event of such amendment, distinction will be made between the initial review question(s) and any subsequent amendment(s) in the report of the review.

Ethics and dissemination plans: This systematic review will use data from published studies; therefore, ethical approval is not required. This review is expected to inform the development of patient education interventions for improving free-living PA in individuals with IC. Review findings will be published in a peer-review journal. Results will also be presented at conferences and, potentially, shared with relevant health authorities. The review will be appropriately updated over time.

DISCUSSION

IC decreases an individual's capacity to engage in PA, potentially leading to deterioration in free-living PA behaviour. Improvement in PA behaviour may be gained through the use of patient education interventions. This systematic review will provide evidence in support of, or against, the hypothesis that interventions with a patient education component can improve the free-living PA behaviour of individuals with IC. This conclusion will be derived from a synthesis of quantitative measurement of PA behaviour outcomes following education interventions and qualitative evidence regarding the effectiveness and compliance with education interventions. Overall, the review will clarify the existing evidence base regarding the effect on PA of patient education interventions, and allow the selection of effective components for future tailored interventions.

Contributors UOA conceived of the systematic mixed-studies review, designed the protocol, developed the search strategy, pilot searched the databases and drafted the manuscript. CAS and PMD contributed to the development of the review protocol, selection criteria, the risk of bias assessment strategy and data extraction criteria, and provided critical revision of the manuscript. CAS and PMD provided critical revision of the search strategy and UOA gave statistical advice. All authors read, provided feedback and approved the final version of the manuscript to be published. UOA is the guarantor.

Funding The first author is being sponsored by the University of Nigeria through the TETFUND for a PhD being conducted at Glasgow Caledonian University. This protocol is part of a work towards the award of his PhD. University of Nigeria will have no input on the interpretation or publication of study results. Glasgow Caledonian University will provide material support in the conduct and management of this systematic review but will have no input on the interpretation or publication of study results.

Competing interests None declared.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement All necessary information is included in this manuscript.

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Ukachukwu Okoroafor Abaraogu, Philippa Margaret Dall and Christopher Andrew Seenan

BMJ Open 2016 6:
doi: 10.1136/bmjopen-2016-011405

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